Remarks

Claims 11-36 are presented for the Examiner's review and consideration. Claims 21 and 22 have been amended, and claims 1-10 have been canceled. Claims 27-36 have been added. Applicants believe the claim amendments and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Double Patenting Rejection

Claims 1-26 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5,163,960. The Examiner stated:

> Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one having ordinary skill in the art to provide the well-known therapeutic agent to the implantable device to promote healing and tissue growth. Further, the claim apparatus is...inherent in the claimed method steps.

In response and in order to expedite the prosecution of this application, Applicants submit herewith a Terminal Disclaimer to obviate this double patenting rejection. It should be understood that this Terminal Disclaimer is being filed to expedite prosecution and should not be construed as an admission that the Terminal Disclaimer is necessary.

35 U.S.C. §103 Rejection based on McDaniel *et al* in view of Greco *et al*

Claims 1-26 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,501,031 to McDaniel *et al* (hereinafter "McDaniel") in view of U.S. Patent No. 4,749,585 to Greco *et al* (hereinafter "Greco"). Specifically, the Examiner stated:

> The patent to McDaniel et al discloses a prosthetic knee implant comprising a heat bondable material. McDaniel [et al] fail to teach the use of a therapeutic agent. However, the use of therapeutic agents in implants is well-known in the art. The patent to Greco et al suggests the use of knee implants treated with an antibiotic agent. It would have been obvious to one having ordinary skill in the art to modify the implant of McDaniel et al with an antibiotic agent to minimize infection of the implant and surrounding tissue.

In response, Applicants respectfully submit that this rejection should be withdrawn.

McDaniel discloses a prosthetic joint comprised of a metal retainer and a plastic bearing portion which is securely interlocked to the metal retainer or metal base support. (col. 2, lines 44-47). The metal retainer or base plate includes a plurality of notches or channel type openings spaced apart around the peripheral edge of the retainer. (col. 2, lines 53-55). The plastic portion is molded integrally onto the metal retainer such that the top surface of the retainer is completely covered with plastic to become the plastic bearing surface of the device. (col. 2, lines 62-65). During the molding process, the plastic flows through the notches and surrounds the upper peripheral edge of the metal retainer, as well as flows to the underside of the upper edge of the retainer. This creates a strong mechanical interlock of the plastic portion to the metal base support. (col. 2, line 67 to col. 3, line 4).

Greco discloses a prosthesis coated with a ionic surfactant, an antibiotic and/or antithrombiotic agent and treated with an immobilizing ionic exchange compound, to remove un-antibiotic bound ionic surfactant. (abstract). In practicing the invention, the prosthesis is first coated with a surfactant. The prosthesis is then soaked in a solution of tridodecylmethyl ammonium chloride (TDMAC) and dried. The surfactant-treated prosthesis is then incubated with a phospholipids vesicle suspension, which may have a net negative or positive charge depending on the charge of the surfactant. The prosthesis is rinsed with water to remove adhering (but not bound) vesicles. The prosthesis is now ready for surgical implantation. (col. 5, line 44 to col. 6, line 28).

In contrast, Applicants disclose assemblies for use in surgical applications in humans. The assemblies may include two components, at least one of which comprises a heat bondable material. (paragraph [0007]). The heat bondable material is preferably a polymeric or composite material suitable for surgical applications and implantations in humans, and may be a biodegradable material. (paragraph [0011]). Examples of assemblies of the present invention include suture fasteners, a metal bone plate which is held to bone by a metal bone screw and a nut of bondable material bonded to the plate to secure the connection, a wedge of bondable material bonded to a metal prosthesis to custom fit the prosthesis, and a surgical implant custom formed by bonding together a plurality of discrete elements one or more of which is bondable. (paragraph [0012]). The assemblies can be made of or include a biodegradable material. They can also include tissue ingrowth promoters, antibiotics, or other additives as desired. (paragraph

[0047]).

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974). Applicants respectfully contend that the combination of McDaniel and Greco does not teach or suggest all the claim elements of the claimed invention. With respect to independent claim 11, Applicants content that neither McDaniel nor Greco teach or suggest an expandable implant. Regarding independent claim 21, Applicants contend that neither McDaniel nor Greco teach or suggest a therapeutic agent included within a polymer material. Rather, Greco teaches an antibiotic coating while McDaniel is silent as to the use of a therapeutic agent. In order to highlight these distinctions, independent claim 21 now recites, *inter alia*, a surgical device including a material bonded to an implant and a therapeutic agent included within the material.

Based on the foregoing, Applicants respectfully submit that independent claims 11 and 21 are patentable over McDaniel in view of Greco. If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Therefore, based on at least their dependencies, Applicants submit that dependent claims 12, 14-20, and 22-26 are patentable as well. In order to expedite prosecution, Applicants have canceled claims 1-10. It should be understood that the cancellation of these claims is not an admission that the claims are not patentable over McDaniel in view of Greco.

35 U.S.C. §103(a) Rejection based on Tormala *et al* or Draenert

Claims 1-26 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,084,051 to Tormala *et al* (hereinafter "Tormala") or U.S. Patent No. 4,373,217 to Draenert (hereinafter "Draenert"). Specifically, the Examiner stated:

> The patents to Tormala and Draenert suggest providing bone implants with [a] metallic core and bioresorbable outer layer. Tormala et al teaches the use of therapeutic agents. It would have been obvious to one having ordinary skill in the art to provide Tormala et al...and Draenert...with a bioresorbable material to allow for tissue growth where the material [has] dissolved.

In response, Applicants respectfully submit that this rejection should be withdrawn.

Applicants recognize that the §103(a) rejection is not based on the combination of Tormala and Draenert. Therefore, Applicants have addressed this rejection as two single-

reference §103 rejections.

Tormala discloses a biocomposite material containing a bioceramic component and a material component. (abstract) The material component of the biocomposite provides the toughness, strength and security of handling, because the strong and tough material component supports the brittle bioceramic component as a consequence of the high strength, toughness and high modulus of reinforcement elements. (col. 7, lines 47-52). The material component comprises essentially resorbable material like polymer, copolymer, polymer mixture and/or ceramic material. (abstract). The resorbable polymer component is resorbed advantageously later away, when its supporting effect is not needed any more because the bone fracture, osteotomy or arthrodesis has been healed. (col. 7, lines 58-61). An advantage of surgical products and devices (implants) which are manufactured of resorbable polymers is the fact that they are removed from the living tissues after they have fulfilled their task without needing a separate removal operation, like the implants which are manufactured of biostable materials (e.g. metals) often need. (col. 5, lines 21-27). Furthermore, it is possible to impregnate the open porosity of the bioceramic with chemical additives which facilitate the cell-growth and/or with antibiotics to prevent the growth of micro-organisms inside of the bioceramic component. (col. 10, lines 19-23).

As previously mentioned, Applicants disclose assemblies for use in surgical applications in humans. The assemblies may include two components, at least one of which comprises a heat bondable material. Another component may be an implant, which may be made of metal. A therapeutic substance may be included within the heat bondable material.

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974). Applicants respectfully contend that Tormala does not teach or suggest all the claim elements of the claimed invention. Regarding independent claim 11, Applicants contend that Tormala does not teach or suggest an expandable implant. With respect to independent claim 21, Tormala does not teach or suggest the use of an antibiotic within the polymeric material component. Accordingly, Applicants have amended claim 21 to include, *inter alia*, that an antibiotic is included within the flowable material.

Draenert discloses an implantation material made from mixing a special tricalcium phosphate in a specific amount and particle size to a conventional bone cement. (col. 2, lines 25-

28). The implantation material is made by adding tricalcium phosphate to a monomer, which triggers polymerization, prior to or after the monomer is mixed with a prepolymer, and uniformly mixing the components together. (col. 2, lines 45-51). The bone cement is then injected to a bone cavity, and after a period of time, the bone cement hardens. (col. 10, line 59 to col. 11, line 4). The porous calcium phosphates are rapidly resorbed in the body and permit a rapid growth of bone tissue into the thus-formed pores of the cement. (col. 3, lines 54-57). An antibiotic may be mixed with the implantation material. (col. 6, lines 33-34).

Applicants respectfully contend that Draenert does not teach or suggest all the claim elements of the claimed invention. Regarding independent claim 11, Applicants contend that Draenert does not teach or suggest an expandable implant. With respect to claim 21, Draenert does not teach or suggest bonding a flowable material to an implant before implanting the device. Accordingly, Applicants have amended claim 21 to include the step of, *inter alia*, bonding the flowable material to the implant prior to implantation in a patient.

Based on the foregoing, Applicants respectfully submit that independent claims 11 and 21 are patentable over Tormala and Draenert. If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). Therefore, based on at least their dependencies, Applicants submit that dependent claims 12, 14-20, and 22-26 are patentable as well. In order to expedite prosecution, Applicants have canceled claims 1-10. It should be understood that the cancellation of these claims is not an admission that the claims are not patentable over Tormala or Draenert.

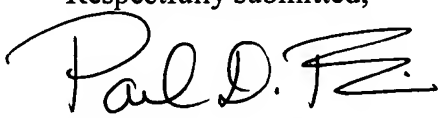
Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of $235.00 for an IDS and a Terminal Disclaimer (small entity rate) is believed to be due with this submission and a Fee Transmittal Sheet including this fee is submitted concurrently

herewith. However, please charge the required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 500601 (Docket no. 780-A02-015-10).

Respectfully submitted,



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